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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Friedrich **MUELLER et al.**

Serial No. **09/971,031**

Filed: October 5, 2001

EXTRACORPOREAL BLOOD TREATMENT SYSTEM

Appeal No:

Examiner:
Confirmation No.
Art Unit:

Skyes, A.
3734
3762

August 11, 2004

U.S. Patent and Trademark Office
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BRIEF OF APPELLANTS

Sir:

This is an appeal from the rejection of the Examiner dated February 13, 2004 finally rejecting claims 1 through 7, the only claims pending in the application.

This Brief, in triplicate, is accompanied by the requisite fee set forth in 37 C.F.R. § 1.17(c). If the fee is insufficient, please charge any additional fee to the account of the undersigned, i.e., 50-1716.

Real Party in Interest (37 C.F.R. § 1.192(c)(1))

The real party in interest is B. Braun Medizintechnologie GmbH, a German corporation having a place of business at Carl-Braun-Strasse 1, 34212 Melsungen, Germany.

Related Appeals and Interferences (37 C.F.R. § 1.192(c)(2))

There are no other appeals or interferences known to Appellants or to Appellants' legal representative or assignee which will directly affect or that will be directly affected by or will have a bearing on the Board's decision in the pending appeal.

Status of Claims (37 C.F.R. § 1.192(c)(3))

Claims 1 through 7 are the only claims under appeal.

Status of Amendments (37 C.F.R. § 1.192(c)(4))

The scope of the claims finally rejected on February 13, 2004 correspond identically to the claims under appeal.

No amendments were presented to the claims after the final rejection of February 13, 2004 though a REQUEST FOR CLARIFICATION (certificate of facsimile on March 16, 2004) and was perfunctorily considered in the Office Action of May 10, 2004.

Upon receipt of the Office Action of May 10, 2004, Appellants filed a RESPONSE AFTER FINAL REJECTION (via certificate of fax), once again absent any amendment of the claims.

Subsequently, the Notice of Appeal was filed.

Claims 1 through 7 set out in the Appendix include all amendments of record and correspond identically to the claims under Final Rejection.

Summary of Invention (37 C.F.R. § 1.192(c)(5))

The invention is directed to a novel and unobvious blood treatment system which comprises an extra corporeal blood (ECB) station 10 which includes an ECB unit 11, such as a dialysis machine and its associated controls. The ECB unit 11 includes a database 12 having a data memory for treatment curves, treatment parameters, ECB machine-related data, etc.

The ECB machine 11 communicates with an internal web server 13 for transferring data/information via a network interface, e.g., an Ethernet interface 16 which includes a Local Area Network (LAN 1) which may itself be part of a global, universal or wide area network (WAN) which is defined by the local area networks (LAN 2, LAN 3, LAN 4, etc.)

An external browser 18 is connected to one of the local data networks LAN 2 via a network interface 17. The term "external" means that the external browser 18 is not provided in the ECB unit 10 shown to the left in the drawing but instead the external browser 18 communicates with the internal web server 13 via the data networks latter described to call information or instructions from the same or to enter such information into the same. The external browser 18 may be physically located at a service center of the manufacturer of the ECB machine 11 or at a central station of the hospital in which the ECB station 10 is operated.

An external web server 20 is connected to the local area data network LAN 3 via a network interface 19. The web server 20 is located at a workstation and inputted thereto are specific patient parameter sets and/or

laboratory data and/or inventory data regarding drugs, filters, etc. The external web server 20 can transmit or renew or update data with respect to the database 12 of the ECB station 10 and accepts parameter sets and/or treatment instructions specific to a patient sent from the ECB station 10.

A further ECB station 2-10 is connected to the local data network LAN 4 which is identical to the ECB station 10, has its own internal browser 2-14, an internal web server 2-13 and an ECB machine 2-11.

In keeping with the invention just described, the same data, information, etc., can be obtained on, for example, a monitor of the user interface 15 of the ECB station 10 under the control of specific code authorizations which permit/deny access.

Though the interface 15 is available to hospital and treatment staff, a second interface 15a which includes a second browser 14a is provided for use by the patient to access the internet.

The scope of the invention claimed, as described, is reflected immediately hereinafter by independent claim 1 to which reference numerals/characters have been added to effect a rapid understanding of the invention and the scope of claim 1:

An extracorporeal blood treatment system comprising an ECB station (10) including an ECB means (11) for extracorporeal blood treatment, an internal web server (13) communicating with the ECB means (11), an internal browser (14) communicating with the internal web server (13), a user interface (15) communicating with the internal browser (14), the internal browser (14) being in communication with external web servers (20) over a data net (WAN; LAN 1-LAN 4) and/or the internal web server (13) being in communication with external browsers (18) via the data net (WAN; LAN-LAN4), and the data communication between the user interface (15) and the ECB means (11) is effected through the internal browser (14).

Issues (37 C.F.R. § 1.192(c)(6))

There is a single issue under appeal, namely the rejection of claims 1 through 7 under 35 U.S.C. § 103(a) which is reproduced immediately hereafter from the Final Office Action of February 13, 2004, paragraph 3 thereof:

3. Claims 1-7 are rejected under 35 U.S.C. 103(a), as being unpatentable over US 6,551,266 to Davis, in view of US Pub. 2003/0154108 to Fletcher-Hayes et al. [sic]. Davis discloses a therapeutic apheresis system, which is an extracorporeal blood treatment machine. The device includes a computerized data management system that includes a system for coordinating, managing, directing, entering, accessing, and analyzing all aspects of remote and local apheresis systems on the network. The device has a CPU and a storage device, as well as all the associated software required to manage and control the system over an Internet platform (see columns 19-21). With that disclosure, Davis indicates that the system incorporates all software and hardware required to establish and maintain an Internet connection. Using the Internet as a communication tool is an obvious solution to communication problems, since the Internet provides a common language that various machines on a network can use to communicate with one another, as taught by Fletcher-Hayes [sic] see paragraphs 0204-0206) [sic]. The communication system used in Fletcher-Hayes' [sic] extracorporeal blood treatment system specifically discloses a web interface that allows communication between a computer/database system and various other computer systems. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the extracorporeal treatment device and computerized data management system disclosed by Davis with the internet [sic] communications software disclosed by Fletcher-Hayes [sic] in order to provide a means of communication that can be decoded by various machines on the network, as taught by Hayes [sic]. Furthermore, it would have been obvious to combine the communications hardware and software in an integrated unit, since it has been held that forming in one piece an article which has formerly been [sic] formed in two pieces and put together involves only routine skill in the art. See MPEP 2144.04. With regard to claims 2-7 regarding the operation of the ECB station and communication system, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. As such, the processes claimed by applicant do not add penetrable weight to the independent claim.

Grouping of Claims (37 C.F.R. § 1.192(c)(7))

Claims 1 through 7 are separately and individually directed to unobvious subject matter and each individually claims unobvious subject matter of the invention recited in claim 1.

Argument (37 C.F.R. § 1.192(c)(8))

There is but a single issue of record, namely, the rejection of claims 1 through 7 "under 35 U.S.C. § 103(a) as being unpatentable over US 6,551,266 to Davis, in view of US Pub. 2003/0154108 to Fletcher-Hayes [sic] et al."

The latter rejection was set forth in the September 12, 2003 Office Action, page 2, paragraph 3, and was repeated verbatim in the Final Office Action of February 13, 2004. The September 12, 2003 rejection was repeated and made Final, even though "Dr. Sandor Dolgos and Peter Szamko, two of the inventors, were kind enough to forward their 'opinion as to how our invention differs from these documents' by way of their letter of November 19, 2003 attached hereto." (See Appellants' Amendment which was certificate of mailed on December 2, 2003, and the letter is also attached to this Brief as Exhibit A.) To quote from the latter Amendment:

First, there is total **agreement** with the view of the Examiner that it would be 'obvious to connect the ECB machines to any computer system using the Internet communication technique' and equally obvious 'to combine the communication hardware and software in an integrated unit'. However, Dr. Dolgos and Mr. Szamko go on to state that the main characteristic of the invention resides in the fact that the 'User interface of the ECB is in close connection with the internal web browser, which yields the information from the internal web server about the therapy.' The latter is expressed in claim 1 by the last limitation reciting:

the data communication between the user interface and the ECB means is effected through the internal browser.

As stated further in Dr. Dolgos' and Mr. Szamko's letter, 'The ECB unit contains an internal web-server and in [sic, "an"] internal web-browser in the same unit (2) and the User Interface is based on the internal web-browser (3).' The conclusion of the inventors is imminently correct, i.e., 'None of the cited documents contain these claim characteristics,' namely, the communication between the user interface (15) and the ECB unit (11) is effected through the Internet browser (14).

The latter-quoted conclusion of Dr. Dolgos and Mr. Szamko remains "imminently correct," and moreover remains uncontradicted on the record, including the Examiner's comments in the Final Office Action, page 4, paragraph 5, which will be considered hereinafter.

Turning specifically to the Final Rejection of February 13, 2004, Appellants agree that the Davis patent discloses exactly that described by the Examiner, namely, "a computerized data management system that includes a system for coordinating, managing, directing, entering, accessing and analyzing all aspects of remote and local apheresis systems on the network." At page 2, beginning at line 3 from the bottom of the Final Office Action and through the next four lines of page 3, the Examiner concluded, absent sound reasoning, that following the Fletcher-Haynes et al. teachings, the Internet could be used "as a communication tool," if one sought an obvious solution to communication problems, since the Internet provides a common language that various machines on a network can use to communicate with one another." However, the issue is not that of machines communicating with one another over the Internet via a common language.

All are in agreement with the Examiner's statement at page 3, between lines 5 and 8 of the Final Office Action that:

The communication system used in Fletcher-Hayes' [sic] extracorporeal blood treatment system specifically discloses a web interface that allows communication between a computer/database system and various other computer systems.

However, independent claim 1 is more specific than mere communication via the Internet.

Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) requires the satisfaction of three conditions in deciding the ultimate question of obviousness/unobviousness, namely, "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and a level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined."

The "scope and content" of the prior art patents to Davis and Fletcher-Haynes et al. are fairly reflected by the Examiner in the Final rejection of claims 1 through 7.

The "differences between the prior art and the claims at issue" were clearly "ascertained" by the undersigned in the Amendment certificate of mailed on December 2, 2003 specifically quoting the last limitation of claim 1 which recites:

the data communication between the user interface and the ECB means is effected through the internal browser.

The undersigned also quoted as being imminently correct the fact that the prior art lacks a suggestion, teaching or motivation of "the communication between the user interface (15) and the ECB unit (11) is effected through the Internet browser (14).

The Examiner never addressed the last limitation of claim 1 nor the fact that the "claimed" characteristics of the last limitation are absent in the prior art and are not suggested, motivated, or taught thereby. Instead, the Examiner presents two arguments in support of the rejection of claim 1 in

the "Response to Arguments" appearing at page 4, paragraph 5 of the February 13, 2004 Final Office Action.

The first argument is a statement alleging that Appellants are predicating obviousness upon features which are not recited in the rejected claims. The example given by the Examiner is "the web server and the web browser in the same machine, with the user interface based on the data communication software." Reference to "in the same unit" comes from a quotation in the letter attached hereto of Dr. Dolgos and Mr. Szamko. It is quite apparent that claim 1 is not limited to an internal web server and an internal web browser in the same machine or unit but is instead based upon the last claim limitation of claim 1 which has been continuously emphasized by Appellants, namely:

the date of communication between the user interface and the ECB means is effected through the internal browser.

The latter was emphasized in the amendment certificate of mailed on December 2, 2003 by the statement:

None of the cited documents contain these **claims characteristics**, namely **the communication between the user interface (15) and the ECB unit (11) is effected through the Internal browser (14)**. (Emphasis added by the undersigned.)

Quite simply, the first argument leaves unaddressed the last limitation of claim 1.

The second of the Examiner's arguments appearing at page 4, paragraph 5 of the Final Office Action of February 13, 2004 is found in the statement:

In particular, the claim limitations set forth only that the various parts of the device are 'communicating' with one another, which is rendered an obvious variation of the prior art of record.

With due respect, if structural limitation in a claim are lacking in the prior art (last limitation of claim 1) and are not rendered obvious thereby, how can specific "communicating" or "communication" with one another be considered "an obvious variation of the prior art of record"?

Returning to claim 1 and the last limitation, all three elements recited therein are earlier recited in the claim and are structurally united by the specific language requiring "data communication between the user interface and the ECB means is effected through the internal browser."

As was noted earlier, the latter limitation was never specifically addressed by the Examiner and nebulous reference to the devices "communicating" with one another fails to address either of "the scope and content of the prior art" or the "differences between the prior art and the claims at issue." (See Graham, *supra*.)

In view of the foregoing reasons, the reversal of the rejection of claim 1 is respectfully requested.

Claim 2 specifies "a central station remote from the ECB station calls and register treatment parameters, treatment results and/or economically relevant data of the ECB operation via the external browser." The latter-quoted limitation of claim 2 remains unaddressed on the record by the Examiner other than by the nebulous "communicating" phraseology appearing in the last sentence of paragraph 5, page 4 of the Final Office Action of February 13, 2004.

Claim 3 recites "a service station remote from the ECB station calls treatment data or operation data from the ECB station via the external browser." The latter-quoted limitation of claim 3 remains unaddressed on the record by the Examiner other than by the nebulous "communicating"

phraseology appearing in the last sentence of paragraph 5, page 4 of the Final Office Action of February 13, 2004.

Claim 4 recites "from a database remote from the ECB station, machine-related, patient-related or drug-related data are transmitted to the internal browser via a web server." The latter-quoted limitation of claim 4 remains unaddressed on the record by the Examiner other than by the nebulous "communicating" phraseology appearing in the last sentence of paragraph 5, page 4 of the Final Office Action of February 13, 2004.

Claim 5, which depends from claim 4, additionally recites "some of the transmitted data are used to set or vary operation parameters of the ECB means." The latter-quoted limitation of claim 5 remains unaddressed on the record by the Examiner other than by the nebulous "communicating" phraseology appearing in the last sentence of paragraph 5, page 4 of the Final Office Action of February 13, 2004.

Claim 6 recites "the internal web server issues an authorization for parameter settings, information access and control operations depending on the identity of the communicating browser or web server." The latter-quoted limitation of claim 6 remains unaddressed on the record by the Examiner other than by the nebulous "communicating" phraseology appearing in the last sentence of paragraph 5, page 4 of the Final Office Action of February 13, 2004.

Claim 7, which depends from claim 2, further recites "a service station remote from the ECB station calls treatment data or operation data from the ECB station via the external browser." The latter-quoted limitation of claim 7 remains unaddressed on the record by the Examiner other than by the

nebulous "communicating" phraseology appearing in the last sentence of paragraph 5, page 4 of the Final Office Action of February 13, 2004.

In view of the foregoing, the reversal of the rejection of each of claims 2 through 5 is considered proper and is respectfully requested.

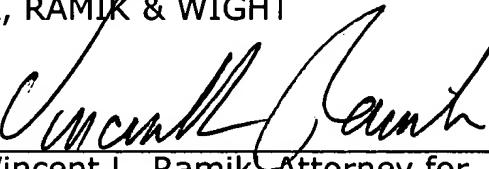
Conclusion

The rejection of record is clearly erroneous for the reasons stated herein, and based thereupon, the Board's reversal of the rejection of claims 1 through 7 is herewith respectfully requested.

Respectfully submitted,

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Attachment: Exhibit A

Appendix (37 C.F.R. § 1.192(c)(9))

Listing of Claims

1. An extracorporeal blood treatment system comprising an ECB station including an ECB means for extracorporeal blood treatment, an internal web server communicating with the ECB means, an internal browser communicating with the internal web server, a user interface communicating with the internal browser, the internal browser being in communication with external web servers over a data net and/or the internal web server being in communication with external browsers via the data net, and the data communication between the user interface and the ECB means is effected through the internal browser.
2. The extracorporeal blood treatment system of claim 1, wherein a central station remote from the ECB station calls and registers treatment parameters, treatment results and/or economically relevant data of the ECB operation via the external browser.
3. The extracorporeal blood treatment system of claim 1, wherein a service station remote from the ECB station calls treatment data or operation data from the ECB station via the external browser.

4. The extracorporeal blood treatment system of claim 1, wherein, from a database remote from the ECB station, machine-related, patient-related or drug-related data are transmitted to the internal browser via a web server.
5. The extracorporeal blood treatment system of claim 4, wherein some of the transmitted data are used to set or vary operation parameters of the ECB means.
6. The extracorporeal blood treatment system of claim 1, wherein the internal web server issues an authorization for parameter settings, information access and control operations depending on the identity of the communicating browser or web server.
7. The extracorporeal blood treatment system of claim 2, wherein a service station remote from the ECB station calls treatment data or operation data from the ECB station via the external browser.

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19.11.2003 15:22

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 Thema: Re: Our US patent application US 910, Extracorporeal blood
 treatment system

Dear Mrs. Vincent,

We reviewed the sent documents (US 2003/0154108 - Fletcher-Haynes and US 6,551,268 - Davis and the Examiner's report and the letter of the US-patent attorney), so please find our opinion as to how our invention differs from these documents.

We found that the cited documents describe medical devices that communicate on a local (non-public) network or on the Internet using standard protocols (HTML, HTTP, TCP/IP).

We absolutely agree with the opinion of the Examiner: It is obvious to connect the ECB machines to any computer system using the internet communication technique. We also agree that it is obvious to combine the communication hardware and software in an integrated unit.

However, the main characteristic of our invention is as follows:
 The User Interface of the ECB is in close connection with the internal web browser, which yields the information from the internal web server about the therapy.

The main characteristic of our invention is that the User Interface of the ECB unit is strictly based on this internal web server-web browser communication.
 It is only a further option to connect the same ECB unit to a local network or even to the Internet using the already existing data communication inside the unit!

To prove that please consider a mind-experiment what would happen if we left out those features:
 - It is not necessary at all to connect these ECB units to a local network, so networking may be left out from the ECB unit.
 - However, it is absolutely necessary to have the internal web server/browser pair, because without them the User Interface of the ECB unit wouldn't work at all!

The advantage of this solution is the following:
 We don't need to develop and maintain the full User Interface of the ECB unit twice: one User Interface for the ECB unit local handling and another remote User Interface for the remote access.
 In our invention both User Interfaces are based on the same internally generated dynamic web-pages.

Of course the use of remote User Interface would be restricted by careful functional authorization for the sake of patient's safety!

Our main claim in EP910 is about the ECB unit's User Interface and how this user interface is built up on which basis.
 The ECB unit contains an internal web-server and an internal web-browser in the same unit (2) and the User Interface is based on the internal web-browser (3).

None of the cited documents contain these claim characteristics.
 Perhaps our main claim should be completed or clarified in order to better emphasize the above mentioned main characteristics of our invention.

Best regards,

Dr. Sandor Dolgos
 Peter Szamko

EXHIBIT

"A"